

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph bridging pages 1 and 2 of the specification with the following amended paragraph:

Based on the National Cancer Institute (NCI) incidence and National Center for Health Statistics (NCHS) mortality data, the American Cancer Society estimated that breast cancer would be the most commonly diagnosed cancer among women in 2002 in the United States. It is expected to account for 31 percent (203,500) of all new cancer cases among women and 39,600 will die from this disease. Jemal A, Thomas A, Murray T, Thun M. Cancer statistics, 2002. *CA Cancer J Clin.* 2002;52:23-47. Presymptomatic screening to detect early-stage cancer while it is still respectable with potential for cure can greatly reduce breast cancer related mortality. Unfortunately, only about 50% of the breast cancers are localized at the time of diagnosis. National Cancer Institute. Cancer Net PDQ Cancer Information Summaries. Monographs on "Screening for breast cancer." <http://cancer.net.nci.nih.gov/pdq.html> (Updated January 2001). Despite the availability and recommended use of mammography for women age 40 and older as a routine screening method, its effectiveness on reducing overall population mortality from breast cancer is still being investigated. K. Antman et al., *JAMA.* 1999;281:1470-2. Currently, serum tumor markers that have been investigated for use in breast cancer detection still lack the adequate sensitivity and specificity to be applicable in detecting early-stage carcinoma in a large population. The FDA approved tumor markers such as CA15.3 and CA27.29, are only recommended for monitoring therapy of advanced breast cancer or recurrence. D.W. Chan et al., *J Clin. Oncology.* 1997;15:2322-2328. New biomarkers that could be used individually or in combination with an existing modality for cost-effective screening of breast cancer are still urgently needed.